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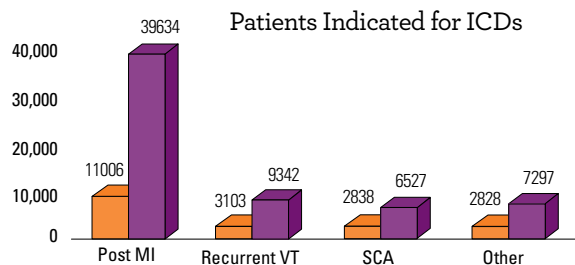
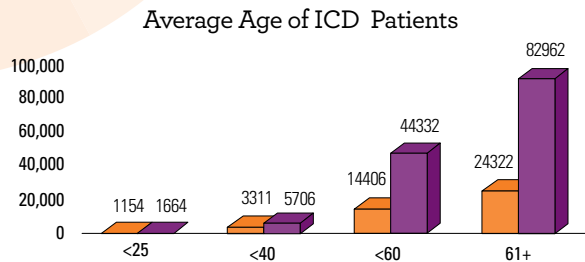
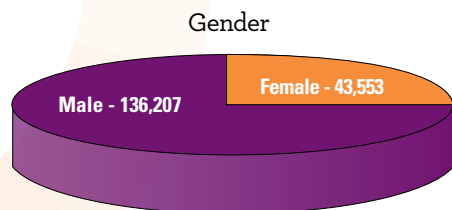
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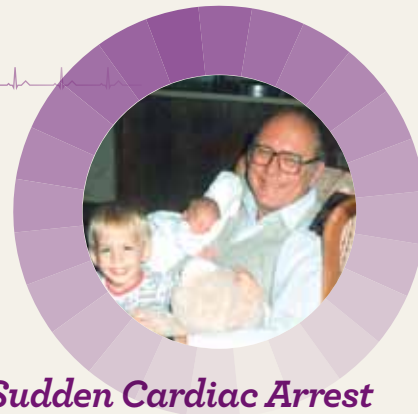
30th Anniversary!

The implantable cardioverter defibrillator (ICD) is designed to treat rapid, irregular heart rhythms. They have been doing so for 30 years.



194,039 Current Implanted ICDs

From the Editor



Sudden and Unexpected = Sudden Cardiac Arrest

In 1987, my father died suddenly at home. He was 57 years old. Since then, ambulance services have portable defibrillators on hand and CPR classes are offered annually in most communities.

The U.S. Congress designated October as "National Sudden Cardiac Arrest Awareness Month" in 2008. Even now, more people die from sudden cardiac arrest (SCA) than AIDS, breast cancer, and lung cancer combined.¹ Sudden cardiac arrest can lead to sudden cardiac death (SCD).

Get the facts:

- SCA strikes without warning: about 295,000 people die each year from SCA.¹
- SCA has known risk factors: if you have survived a heart attack and have a lower ejection fraction (EF), you are at risk for SCA.² Your doctor can measure your EF with a simple test.
- Sudden Cardiac Death is preventable: ICDs have been shown to prevent SCD for 30 years.²

We have more information about sudden cardiac death on our new website, www.lifebeatonline.com. Let us know what you think.



Go to LifeBeat Online and click "Contact Us" to submit a question.



Call Patient Services at 1.866.484.3268 to submit a question to LifeBeat.



Write to us at 4100 Hamline Ave. North, MS 5-393, St. Paul, MN 55112-5798.

Thank you for reading LifeBeat.

Barbara Gaynor, M.S.
Patient Advocacy and Education

1. American Heart Association. Heart Disease and Stroke Statistics – 2010 Update. *Circulation*. 2010;121:e1-e170.
2. Goldenberg I, Gillespie J, Moss A. Long-term benefit of primary prevention with an implantable cardioverter-defibrillator. An extended 8-year follow-up study of MADIT II. *Circulation*. 2010;122:1265-1271.

Vitamins and Supplements

In the last 20 years, an increasing number of Americans are taking some form of dietary supplement like vitamins, herbals, and enzymes. They spend billions of dollars each year in the hope that these products will help them maintain good health and well being.¹

What is a dietary supplement?

A dietary supplement is a product consumed to provide a health benefit other than nutrition. It contains one or more “dietary ingredients.” Foods like meat, fish, and vegetables are not dietary supplements since they are eaten primarily for their nutritional value.

Are dietary supplements regulated by the FDA?

While dietary supplements are under the “umbrella” of foods, there are no regulated manufacturing standards in place for many herbal compounds. The U.S. Food and Drug Administration (FDA) works to assure that the food supply is safe, sanitary, wholesome, and honestly labeled. Since the Dietary Supplement Health and Education Act (DSHEA) of 1994, the FDA must prove that a supplement presents a safety risk, makes false or misleading claims, or is otherwise misbranded. In effect, DSHEA makes it more difficult for the FDA to challenge claims for health benefits made by supplement manufacturers, even if the claims of health benefits have not been fully proven. This is quite different from the strict control the FDA has over prescribed and over the counter medications.

A few cautionary notes:

Always let your doctor(s) know when you are taking supplements, especially if you have a chronic disease or are taking prescribed medications. Do not ignore medical advice or take supplements in lieu of medicine prescribed by your doctor.

For more information on a healthy diet, talk to your physician. Other resources include:

- National Institutes of Health, Office of Dietary Supplements, <http://ods.od.nih.gov/>
- FDA Center for Food Safety and Applied Nutrition, call 1-888-723-3366 or <http://www.cfsan.fda.gov/~dms/supplmnt.html>

Why should someone take supplements for their heart?

Some people take dietary supplements to reduce their risk for heart attacks, colds, stress, and flu. Other people take supplements to increase their energy levels. For example, if you know that you have high cholesterol, your healthcare provider may adjust your diet as one type of treatment. For many people, making lifestyle changes is enough to lower cholesterol. Other people need medications like cholesterol-lowering statin drugs. Dietary supplements can be a part of that prescription, too.¹

Do supplements interact with heart medicines?

Supplements and herbal remedies contain active ingredients – naturally occurring chemical substances that can have a powerful affect on the body. However, because supplements can affect your body in different ways, or can interact with your prescription medications, you should be careful when considering taking supplements.

Tell your doctor if you take any vitamins or herbal supplements, and always talk to your doctor before beginning to take a new vitamin or herbal supplement. Although your doctor may agree that a particular supplement may be helpful for you, sometimes he or she may ask that you not take a particular supplement.

Table 1 covers several common dietary supplements and their effects and potential interactions with heart medicines.

This is not a complete list of side effects and others may occur. Tell your doctor, pharmacist, herbalist, or other healthcare provider about any unusual or bothersome side effect. You may report side effects to FDA at 1-800-FDA-1088.

Table 1. Brief Overview of Popular Vitamins and Supplements

Supplement	Potential Benefits	Known Adverse Effects	Drug Interactions
CQ10: Coenzyme Q10 is produced by the body and is necessary for basic cell functioning.	May reduce chest pain (angina) for people with clogged arteries, may make exercise easier.	Rare, but side effects include heartburn, nausea, stomach ache, diarrhea, headache, fatigue, and skin reactions.	May interact with blood thinners.
Ephedrine and ephedra-containing herbal supplements.	Ephedrine (drug) is used in the treatment of asthma and bronchitis. Ephedra-containing herbal supplements (e.g., ma huang, Indian joint fir) are used for asthma, the common cold, hay fever, and weight loss.	May cause heart arrhythmias, chest pain (angina), sweating, nausea, restlessness, shortness of breath, headache, and tremor.	Not to be used by patients taking antidepressant medicines (SNRIs). Used with caution in patients with diabetes mellitus, cardiovascular disease. Side effects may increase for patients taking beta blockers.
Ginkgo: herb from the leaves of the ginkgo biloba tree.	May improve blood flow in the brain and elsewhere in the body, reduce inflammation, and improve memory.	Very rarely associated with allergic skin reaction, chest pain, nausea, and headache.	Not recommended for patients using aspirin, blood thinners, or nonsteroidal anti-inflammatory drugs (e.g., ibuprofen, Advil®).
Omega-3 fatty acids found in certain types of fish, vegetables, and plants.	Has been used with diet, exercise, and medical care to reduce triglyceride levels and increase good HDL cholesterol.	Fishy aftertaste (if your product is made from fish oil), nausea, bloating, or burping may occur.	May interact with medications that "thin" the blood (such as anticoagulant and antiplatelet drugs) and increase the risk of bleeding.

Supplement	Potential Benefits	Known Adverse Effects	Drug Interactions
Red yeast rice is a product of yeast that is grown on rice.	Has been used with diet, exercise and medical care to reduce levels of "bad" (LDL) cholesterol and triglyceride levels in the blood and increase good HDL cholesterol.	Side effects may include upset stomach, heartburn, muscle and kidney and liver damage. Do not take red yeast rice if you are allergic to it, or if you have a history of liver disease.	May increase the effect of cholesterol lowering medications (e.g. atorvastatin (Lipitor™), lovastatin (Mevacor™), pravastatin (Pravachol™) and raise the risk of side effects such as liver damage. Red yeast rice used with warfarin may increase the risk of bleeding.

Read more: PDR for Nutrition and Supplements³ and the PDR for Herbal Medicines.⁴

Eating Right

Eating a balanced diet in our modern society takes some commitment and discipline.... and can be very difficult to achieve.

The Atherosclerosis Risk in Communities Study (ARIC) of 15,700 adults found four factors for adapting a healthy lifestyle:⁵

- *Eating at least five fruits and vegetables daily*
- *Walking or getting other exercise for at least 2.5 hours weekly*
- *Keeping BMI (body mass index) out of the obese range (≥ 30)*
- *Don't smoke*

1. National Institutes of Health, Office of Dietary Supplements. NIH Publication 10-7527; January 2010.

2. Drugsite Trust. Drug Information Online at www.Drugs.com. Accessed August 2010.

3. PDR for Nutrition and Supplements, 2nd ed. Physicians' Desk Reference, Inc.: Montvale, NJ, 2008

4. PDR for Herbal Medicines, 4th ed. Thomson Reuter (Healthcare): Montvale, NJ, 2007

5. King, D. Turning back the clock: Adopting a healthy lifestyle in middle age. *American Journal of Medicine*, 2007; 120:598-603.

Radio Frequency Identification

Retail shops, self-service kiosks and shopping centers have one thing in common. They all use security systems at each store entrance. These systems use either radio or electromagnetic waves to detect a tiny sensor on a product or store merchandise. If the sensor is left in place when the product passes through a security system, the alarm senses the tag. It beeps or lights up to alert security workers.

A growing number of products on the shelf have a small piece of technology attached to the label or the product itself. This technology is a radiofrequency identification (RFID) tag (Figure 1).

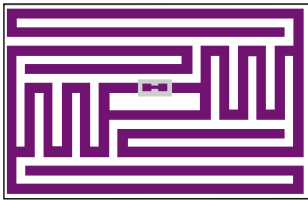
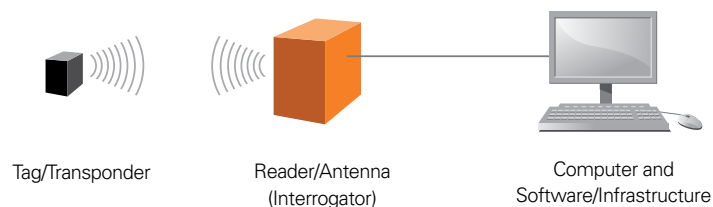


Figure 1. An electronic product code RFID tag used by Wal-Mart.

What is RFID?

Radiofrequency identification (RFID) is a tool for identifying and tracking items or people. In an RFID system, a small memory-storage chip (tag) is placed on an item. RFID readers send out radio waves to detect the tags and read their data (Figure 2). This information helps the retail store manage inventory and prevent theft.

Figure 2. An example of an RFID system.¹



RFID systems are used in many places. Some examples include:

- Stores, warehouses and shipping area for inventory control
- Worksites for employee identification
- Transportation systems for fare collection, such as subway stations and toll booths
- In healthcare facilities to ensure patients receive the correct medicine and device therapies

What is the potential for RFID to interact with an implanted device?

An interaction between an RFID reader and an implanted medical device is unlikely, unless the patient is standing close to an RFID reader. Some RFID readers may produce electromagnetic fields large enough to interact with an implanted cardiac device within a short distance. Table 1 has suggested separation distances for cardiac device patients when near RFID readers.

Table 1. Separation Distances Suggested for Patients Implanted with Boston Scientific Devices

Device Type	Separation Distance
Pacemakers	INSIGNIA® and ALTRUA®: 1.5 ft (40 cm) All other Boston Scientific pacemakers: 2 ft (60 cm)
ICDs, CRT-Ds, and CRT-Ps	6 in (15 cm)

Should patients be concerned with RFID tags?

To date, RFID tags have not been identified as sources of EMI to implanted cardiac devices.

Is RFID utilized in bar code readers?

No. Bar code readers use visible light to perform their designed function and are not a source of EMI to implantable pacemakers or defibrillators.

Who should patients talk to regarding potential EMI and their implanted device?

Patients should talk to their physician if they have any questions specific to their implanted device, including EMI-related topics.

Learn More

Sources of Electromagnetic Interference (EMI) offers guidelines to help you identify types of equipment and tools that are safe to use near cardiac devices, as well as the types to avoid. It is available online at www.lifebeatonline.com in the Daily Living section.

1. Association for Automatic Identification and Mobility. What is RFID? Available at www.aimglobal.org/technologies/rfid/what_is_rfid.asp. Accessed August 2010.

Who gets a device?

What Is a Clinical Study? Part 3

A clinical study, or trial, is a scientific study that can involve people. You may hear that a new study was published. You may hear that a product was shown to help patients based on clinical research. In this article, we look at how clinical information can lead to more options for patients with heart disease. We shall also talk to a patient who has benefitted from a clinical study.

When a new therapy is proven to be a safe and effective treatment for certain patients, then it is considered “indicated” or appropriate for those types of patients to get the treatment.

Decreased Risk of Death in Heart Attack Survivors: The MADIT II Study

Many heart attack survivors die within five years of their first heart attack.¹ The MADIT II clinical study compared heart attack survivors treated with an implantable cardioverter defibrillator (ICD) device and heart medication to heart attack survivors on heart medication alone. The trial showed that heart attack survivors treated with an ICD and medication had a 49% risk of death compared to 62% risk of death for heart attack survivors on heart medication alone. These results confirmed that ICDs can save lives.²

Extending the Lives of Heart Failure Patients: The COMPANION Study

The COMPANION study focused on people with symptoms from heart failure (NYHA Class III and IV) even when treated with heart medications. Patients treated with a cardiac resynchronization therapy-defibrillator (CRT-D) device and medication lived longer than those treated with medication only. The study also found that people who received CRT therapy had fewer symptoms and reported a better quality of life. As with the standard ICD, CRT-D therapy saves lives, and offers heart failure patients improved quality of life.³

Helping Heart Patients Before They Feel Symptoms: MADIT-CRT

Heart failure is a progressive and complex disease. In the early stages of heart failure, you may not feel sick. However as the disease progresses, your chances of spending time in the hospital increases. In MADIT-CRT, patients in the early stages of heart failure or mild heart failure (NYHA Class I and II) were treated with an ICD device and medication or a CRT-D device and medication. The study found that the addition of CRT therapy reduced the risk of a hospitalization or death by 57% for certain patients.⁴ MADIT-CRT results show that early intervention with CRT-D therapy can help patients live longer and reduce hospitalizations for heart failure.

1. Lloyd-Jones D, Adams RJ, Brown TM, et al. Heart Disease and Stroke Statistics—2010 Update. *Circulation*. 2010;121:e1-e170. On the basis of data from the FHS of the NHLBI.

2. Goldenberg I, Gillespie J, Moss AJ, et al. Long-term benefit of primary prevention with an implantable cardioverter-defibrillator – An extended 8-year follow-up study of MADIT II. *Circulation*. 2010;122:1265-1271.

3. Bristow MR, Saxon LA, Boehmer J, et al. Cardiac-Resynchronization Therapy with or without an Implantable Defibrillator in Advanced Chronic Heart Failure. *N Engl J Med*. 2004; 350:2140-2150.

4. Moss AJ, Hall WJ, Cannom, DS, et al. Cardiac-resynchronization therapy for the prevention of heart-failure events. *N Engl J Med*. 2009 ;361(14):1329-38.



MADIT-CRT Patient:

Claudette Thornton, age 66



5 years ago, Claudette realized that performing her favorite past time, singing, was not the same. She couldn't hold her breathe to sing like as she used to. And it was harder to replicate a note that she heard. She sometimes felt a little more tired than usual, or felt like sitting versus taking a walk. Claudette chalked it up to getting older.

"I didn't have any concerns," Claudette said. "There were no sudden changes. No worries. At least not until that night at the Detroit Piston's game." Claudette went to the evening event with her husband. After the game, she doesn't remember if the team won or lost. She remembers suddenly feeling too tired to walk! Her husband, Miguel, didn't think twice; he took her to the hospital immediately.

"I didn't have any pain. Nothing about it felt urgent. But we talked to the doctor that night. He looked at me and thought about my heart. We did a few tests, and then went to an exam room to get a picture of my heart from the inside. It was called an echocardiogram."

Claudette's heart was a little larger than normal. In addition, it was not beating normally. One side of her heart beat at a regular rate, but the other side was always off. Three months later, in December 2005, Claudette entered the MADIT-CRT clinical study.

"I wasn't worried at all about having surgery to get my device. I think back now and realize why. My doctor told me everything that was going to happen. The people at the hospital were very kind before and after the surgery. They were truly concerned about me. It was like a gift."

Her device has been treating her heart failure for the last five years. "I never felt like I was part of an experiment. Each time I went in to have my device checked, it was all about me. I felt very relaxed."

Claudette spends her time with travel, gardening, and singing. "I can't sing like I used to when I was younger, but I am back to enjoying performing my music."

Do All Heart Failure Patients Benefit From CRT?

No, not everyone will benefit from a CRT device. In general, patients who are more likely to benefit from a CRT device are those with:

- Heart failure with moderate to severe symptoms (for example, difficulty breathing or extreme tiredness) despite other treatments (NYHA Class III-IV), or heart failure with mild symptoms (NYHA Class II), or heart failure from coronary heart disease with no symptoms (NYHA Class I)
- A measured ejection fraction of 35% or less
- An electrical problem that causes uncoordinated pumping of the ventricles called left bundle branch block LBBB

Cardiac resynchronization therapy devices are not for everyone. Patients who respond well to other treatments, such as lifestyle changes and medication, may not need a CRT device. Your doctor can tell you whether a CRT device may be helpful or right for you. You and your doctor can also discuss important safety information related to this device.

**Know your risk factors –
Talk to your doctor –
Take charge of your heart health**



Did you know that heart disease causes more deaths in Americans of both genders and all racial and ethnic groups than any other disease?¹ Close the Gap (CTG) is an educational initiative sponsored by Boston Scientific and led by a team of physicians and healthcare professionals from across the United States. CTG addresses disparities in cardiovascular care for women, black Americans, and Hispanic/Latino Americans.

Close the Gap focuses on three areas: community education, patient values, and quality measures.

Community Education

- Close the Gap educates a variety of audiences about how race, ethnicity, and gender can affect a person's risk of developing heart disease. By increasing awareness of risk factors, CTG hopes to identify and help more high-risk patients.

Patient Values

- Close the Gap helps health care providers learn about the cultural beliefs and barriers people associate with heart disease treatments. When cultural barriers are understood and addressed, patients are better able to communicate with their doctor and receive proper cardiovascular therapies.

Quality Measures

- Close the Gap works to help raise awareness of evidence-based medicine for treating heart disease. By focusing on proven medical treatments, effective treatments can be used to extend and improve the lives of all patients who would benefit from them.

For more information on heart health, disparities in cardiovascular care, and Boston Scientific's Close the Gap educational initiative, visit www.your-heart-health.com.



View our videos on
[YouTube](#)



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Close the Gap on
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Important Safety Information

Cardiac Resynchronization Therapy Devices from Boston Scientific CRM

Cardiac resynchronization therapy pacemakers (CRT-P) and defibrillators (CRT-D) are designed to treat heart failure patients who may or may not have symptoms (CRT-D), or who may have symptoms despite the best available drug therapy (CRT-P and CRT-D). They are also designed to help your heart pump more effectively and meet your body's need for blood flow. CRT-P and CRT-D systems are not for everyone, including people with separate implantable cardioverter-defibrillators (CRT-P only) or certain steroid allergies. Procedure risks include infection, tissue damage, and kidney failure. Patients who should not receive this device include: patients who have additional medical conditions that may not allow the pacemaker to function appropriately (CRT-P only) and patients whose ventricular rhythm disturbances or heart failure have a reversible or temporary cause. In some cases, the device may be unable to detect or appropriately respond to your heart rhythm (CRT-P and CRT-D) or may deliver inappropriate shocks (CRT-D only). In rare cases severe complications or device failures can occur. Electrical or magnetic fields can affect the device. Only your doctor knows what is right for you. These devices are available by prescription only. Individual results may vary. Your physician should discuss all potential benefits and risks with you. For further safety information, refer to the Physicians Instructions for Use or call 1/866-484-3268.

(Rev. G)

Implantable Cardioverter Defibrillators from Boston Scientific CRM

An implantable cardioverter defibrillator is designed to monitor and treat heart rhythm problems, greatly reducing the risks associated with them. But it is not for everyone, including people with certain steroid allergies. Procedure risks include infection, tissue damage, and kidney failure. Patients who should not receive this device include: patients whose ventricular rhythm disturbances have a reversible or temporary cause and patients with certain types of atrial rhythm disturbances. Procedure risks include infection and tissue damage. In some cases, the device may not respond to irregular heartbeats or may deliver inappropriate shocks. In rare cases severe complications or device failures can occur. Electrical or magnetic fields can affect the device. Only your doctor knows what is right for you. This device is available by prescription only. Individual results may vary. Your physician should discuss all potential benefits and risks with you. For further safety information, refer to the Physicians Instructions for Use or call 1/866-484-3268.

(Rev. G)

Pacemakers from Boston Scientific CRM

A pacemaker system is designed to monitor and treat your heart rhythm problems, greatly reducing the risks associated with them. But it is not for everyone, including patients with certain steroid allergies. Procedure risks include infection, tissue damage, and kidney failure. Patients who have additional medical conditions that may not allow the pacemaker to function appropriately should not receive a device. In rare cases severe complications or device failures can occur. Electrical or magnetic fields can affect the device. Only your doctor knows what is right for you. This device is available by prescription only. Individual results may vary. Your physician should discuss all potential benefits and risks with you. For further safety information, refer to the Physicians Instructions for Use or call 1/866-484-3268.

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Delivering what's next.™

Cardiac Rhythm Management

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LifeBeat has a new look. Boston Scientific's Cardiac Rhythm Management Group (pacemaker and defibrillators for the heart) has joined the Cardiovascular Group (stents for the heart and body).

We are now called the Cardiology, Rhythm and Vascular (CRV) Group. LifeBeat will grow to talk to more types patients living with CRV therapies. If you have any questions, please call 1.866.484.3268.